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The following comments are submitted regarding FSIS Docket No. 98-045N3 and FDA Docket No. 00N-0504 entitled "Egg Safety Action Plan."

Comments on the President's Council on Food Safety,
Egg Safety Action Plan to Eliminate *Salmonella enteritidis* Illnesses Due
to Eggs

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The goal of the Egg Safety Action Plan to achieve a 50 percent reduction of egg-associated SE illnesses by the year 2005 is reasonable and achievable. In recent years, there has already been a significant decline in such illnesses. In fact, the number of human SE illnesses is declining in all regions of the United States.

It would be impossible to accurately assign credit for this decline but it would be logical to recognize the impact of the Egg Quality Assurance programs that have been implemented by many egg producers and the improved methods of handling and preparing eggs for consumption. The increased awareness of the important role of food handling and preparation in food safety has come from years of attempts by government agencies and industry to inform and educate those in food service on the use of eggs.

Many of the Egg Quality Assurance programs include the provisions for testing the environments of laying hens and diverting the eggs of SE positive houses from shell egg sales to breaking and pasteurization. This is the final step after all the other provisions of the Egg Quality Assurance program have failed to keep the flock free of SE.

Regardless of how one assigns credit for the decline in SE, the decline is occurring. Even though the proposed goal of a 50 percent reduction in SE

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egg-related illnesses has as its baseline the lower rate that now exists, it will doubtless be achieved if the current rate of decline continues. In fact, that likelihood relates to the U.S. Poultry & Egg Association's suggestion on the Egg Safety Action Plan that is presented in this letter.

We suggest that the federal agencies involved, but with the addition of another agency, USDA-APHIS-VS, proceed with the development of a regulation utilizing the public comment provision from all concerned parties. However, rather than immediately implementing the regulation upon its completion, the agencies would put the regulation on "stand-by" status to be put in force only if the 50 percent reduction goal is not met by 2005. If, however, the goal is met, allow the industry to continue its efforts (which appear to be working) toward further reductions.

As for the total elimination of egg-related illnesses by the year 2010, this is probably an unrealistic expectation unless there is some type of technological breakthrough in vaccines, premise decontamination or in some unforeseen final intervention strategy. Even if all shell eggs were to be pasteurized and free of SE, because of problems such as the known close relationship between SE and rodents like mice, it is reasonable to predict that the contents of SE-clean eggs will occasionally be contaminated during preparation for serving and result in some human illnesses that epidemiologically would be related to the consumption of eggs. Your report also states that there are 65,000 egg producers in the United States with 3000 or fewer hens. These producers would likely not be included with those to which the regulation would apply and could certainly be a source of egg-related SE. For these and other reasons, it would be an unrealistic expectation to set total elimination of egg-related human illnesses by 2010 as an achievable goal.

In addition to bringing in the farm knowledge that USDA-APHIS-VS can contribute to the development of the production-related regulations, there should be other regulations put in place. There is no reason why FDA cannot transition the industry-supported Food Code recommendations of substituting pasteurized liquid egg for the breaking and pooling of shell eggs in institutions caring for the elderly and ill into a regulation. In fact, it would be appropriate to extend such a regulation to include all institutions like prisons, which serve very large numbers of people and therefore require large quantities of food. If the in-shell pasteurization of eggs turns out to be a feasible, workable process that accomplishes what it is touted to do, such eggs could also be required in such institutions for the individual egg servings.

We concur on the research priorities and urge that the appropriate funding be allocated for that purpose. Because the very large, multi-age egg complexes housing over one million layers on a single premise cannot be effectively cleaned and decontaminated, effective vaccines may be the only realistic intervention strategy available for such operations. Vaccines, therefore, should be a very high research priority. That would include the relative merits of types of vaccine (killed vs. viable), the vaccination schedules, routes of administration, etc. on the deposition of SE in eggs by SE-exposed hens. A difficulty in determining the efficacy of SE vaccines in preventing or reducing

the number of SE-contaminated eggs relates to the very low numbers (2-3/10,000) of contaminated eggs laid by infected but unvaccinated flocks. For that reason, it may require many replications and large numbers of hens to get a clear assessment of the true benefits of vaccine use.

Similarly, induced molting is of critical economic importance to the egg industry. If it is reliably revealed by carefully controlled, well designed studies that molted hens lay more SE-positive eggs during the first 30 days after resuming lay, for example, those first eggs can be routinely diverted to pasteurization. The industry just needs sound research data acquired in a realistic setting with naturally infected hens to guide them in making such decisions.

In fact, the long list of research priorities in the subject Egg Safety document indicates that a lot more information is needed to formulate a truly science-based SE regulation. It would be a serious error to get the regulation ahead of the science needed to support and justify it.

There are additional steps that the egg industry can and should take that may help in maintaining the present decline in egg-related human illnesses. The industry can make an effort to pack less than the allowable limit of cracked eggs in the carton. Cracked eggs can provide an additional avenue for SE to gain access to the internal contents of the egg. They can step up their testing program in high-risk situations and divert eggs that pose an increased consumer risk to pasteurization. This increased level of testing will indicate to the industry where additional interventions are appropriate such as clean-out, decontamination, and vaccination. Decontamination of SE-negative layer houses simply because it is required by an all encompassing regulation will not reduce the incidence of egg related SE illnesses in humans. The industry also can do a more effective job of promoting the use of pasteurized liquid egg products instead of the breaking and pooling of eggs and try to make such products more widely available to consumers in small carton quantities.

The in-shell pasteurization of eggs may eventually enable the industry to offer this product for general consumer use at a premium price. High-risk consumers and those who desire to use raw egg recipes should have the option of buying that product. Since the technology is relatively new and in the early stages of implementation, there may be unexpected complications that will require time to resolve. Because of the high cost of the equipment and the process rate, which is far slower than the other steps in the processing chain, it will not be realistic to expect that this will be a universal addition to egg processing.

The integrity of the yolk membrane that separates the nutrients of the yolk from the albumen, which is where any SE, if present, would be located, is of great importance to egg safety. The time and temperature of egg storage is the major influencing factor on the integrity of the yolk membrane. In addition to refrigerating eggs, the industry needs to implement a scheme of egg dating so that the age of the egg or use-by dates can readily be determined at any stage of marketing or use. The producer code could

accompany that information to facilitate tracing to the source should illnesses occur. If there are problem flocks that are contributing to the numbers of human illnesses, it is in everyone's best interest for them to be quickly identified without so much "blind" testing of flocks.

In response to some of the specific questions (question #4) posed in the Federal Register notice of public meeting, March 21, 2000, there have been no indications that feed is a significant source of *S. enteritidis* in chickens. Therefore, efforts directed at this possible source will not yield a reduction in egg related human illnesses. The same is true for water supply monitoring or broad flock health monitoring. Environmental monitoring of fecal droppings to indicate SE flock status and effective rodent control programs are known to be beneficial. As stated elsewhere in these comments, there is nothing to be gained by the cleaning and disinfection of SE-negative layer houses.

The question #7 addressing what steps should be required of a producer when a house/flock is SE-positive is difficult to respond to. This is the most perplexing challenge facing the industry regarding SE. It is virtually impossible to adequately clean and disinfect some layer houses, depending upon their construction, location, size, etc. to guarantee that no SE remains in the house or in rodent burrows that could infect the replacement pullets. In addition to cleaning and disinfection steps that will hopefully lower the number of SE present, the proper immunization of the replacement pullets before their arrival is the only other intervention strategy that offers much hope at the production level. Such a scenario as presented in question #7 emphasizes the need for comprehensive third-party data on the efficacy of the SE vaccines, live and inactivated, in preventing or reducing the deposition of SE in eggs.

In summary, because the decline in egg-related human illnesses is well underway, allow the decline to continue without inserting regulations that may not be needed to achieve the 50 percent reduction by the 2005 goal. Such a regulation will be costly, may exceed our laboratory capabilities, and may be very disruptive to an industry that is not presently in a good state of economic health. It should also be recognized that the marked diversity of the egg industry will complicate the formulation and implementation of a comprehensive regulation intended to address the SE problem from farm to table. Some very large companies have extensive breaking/pasteurization capacity while other large companies have very little or none. There are multiple-age farms containing millions of layers in 100,000 bird houses directly connected to a processing facility and there are small contract growers that only send eggs to the processing plant several times a week for washing, sanitizing, and packaging. During the development of any large-scale egg regulation, it is important to recognize the extensive diversity of this industry which will prohibit the "one size fits all" approach.

Bring USDA-APHIS-VS into the picture to utilize their wealth of knowledge and experience in on-farm disease control programs and to assist in the development of a SE regulation from farm to table, considering comments/suggestions from all those concerned. Set the regulation aside, allow the present practices to continue with the improvements that will certainly emerge, and monitor the trends of egg-related human

illnesses due to SE. If the illnesses start up significantly, implement the regulation. If the rate of human illness continues on the present downward trend, the regulation may never have to be put in force to achieve the 2005 goal. It seems inappropriate to base the success or failure of the program only on the incidence of human illnesses when the handling and preparation of eggs is so important in causing illnesses but is beyond the control of the egg industry. As inappropriate as the plan appears, we can offer no alternative way to measure the success of a SE control program at this time.

Finally, there is no group that has more to lose or wants to put the SE problem behind them more than the egg industry. If they can do it without a massive new regulation, they should be allowed an opportunity to achieve the same goals as presented in the President's Council on Food Safety Report. The ready-to-be-implemented regulation sitting on the table will provide ample pressure on the industry to get the job done. In addition, the liability concerns, economic pressure, and lastly the more important concern of the public's health will keep all commercial egg producers adequately motivated to finish the task. It is a reasonable and defensible approach, especially considering the recent declining trends of egg-related human illnesses as documented by the CDC.

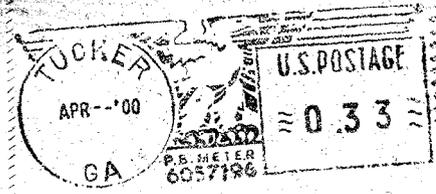
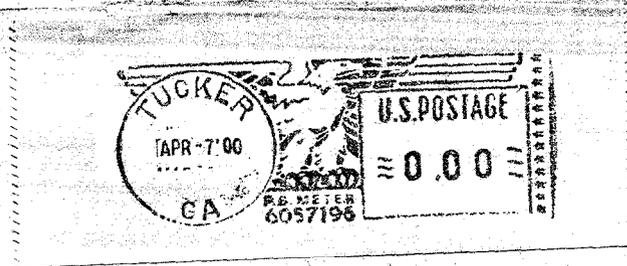
Thank you for the opportunity to comment on the Egg Safety Plan.



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